

AMENDED IN ASSEMBLY JUNE 25, 1998

AMENDED IN SENATE MARCH 17, 1998

SENATE BILL

No. 1606

Introduced by Senator Lewis

February 11, 1998

~~An act to add Article 12.5 (commencing with Section 4177) to Chapter 9 of Division 2 of the Business and Professions Code, relating to pharmacy. An act to amend Section 1261.5 of, and to add Section 1261.6 to, the Health and Safety Code, relating to health facilities.~~

LEGISLATIVE COUNSEL'S DIGEST

SB 1606, as amended, Lewis. Pharmacy: automated drug delivery systems.

Existing law, the Pharmacy Law, provides for the licensing and regulation of the practice of pharmacy, under the jurisdiction of the California State Board of Pharmacy. It prescribes requirements for the dispensing of drugs, as specified.

~~This bill would authorize, with respect to an agreement between a pharmacy and health facility, defined to include convalescence and rehabilitation facilities, the administration of drugs from an automated drug dispensing system in the facility, subject to specified conditions.~~

Existing law provides for the licensing and regulation of health facilities, including skilled nursing facilities and intermediate care facilities, administered by the State Department of Health Services.

Existing law limits the number of oral dosage form or suppository form drugs provided by a pharmacy to a skilled nursing facility or intermediate care facility for storage in a secured emergency supplies container to 24 and authorizes the department to provide for other specified limitations.

This bill would provide, commencing July 1, 1999, that limitations imposed pursuant to these provisions on the number or quantity of oral or suppository form drugs provided by a pharmacy to a skilled nursing or intermediate care facility shall not apply to an automated drug delivery system, as defined by the bill, when a pharmacist controls access to the drugs.

The bill would also provide, commencing July 1, 1999, that access to an automated drug delivery system shall be limited to personnel authorized by law to administer drugs and who have an access code to these systems, would set forth requirements of a health facility and pharmacy with regard to the installation, operation, and review of an automated drug delivery system, and would exempt an automated drug delivery system from certain drug labeling requirements.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

1 ~~SECTION 1. Article 12.5 (commencing with Section~~
 2 ~~SECTION 1. Section 1261.5 of the Health and Safety~~
 3 ~~Code is amended to read:~~
 4 ~~1261.5. Notwithstanding Section 72377 of Title 22 of~~
 5 ~~the California Code of Regulations, the (a) The number~~
 6 of oral dosage form or suppository form drugs provided
 7 by a pharmacy to a health facility licensed pursuant to
 8 subdivision (c), (d), or both (c) and (d), of Section 1250
 9 for storage in a secured emergency supplies container,
 10 pursuant to Section 4035 of the Business and Professions
 11 Code, shall be limited to 24. The State Department of
 12 Health Services may limit the number of doses of each
 13 drug available to not more than four doses of any separate
 14 drug dosage form in each emergency supply.

(b) Any limitations established pursuant to subdivision (a) on the number and quantity of oral dosage or suppository form drugs provided by a pharmacy to a health facility licensed pursuant to subdivision (c), (d), or both (c) and (d) of Section 1250 for storage in a secured emergency supplies container shall not apply to an automated drug delivery system, as defined in Section 1261.6, when a pharmacist controls access to the drugs. This subdivision shall become operative July 1, 1999.

SEC. 2. Section 1261.6 is added to the Health and Safety Code, to read:

1261.6. (a) For purposes of this section and Section 1261.5, an “automated drug delivery system” means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs and that collects, controls, and maintains all transaction information so that it accurately reflects the complete removal of drugs and provides for security and accountability of drug products.

(b) Access to an automated drug delivery system shall be limited to personnel authorized by law to administer drugs and who have an access code to the system.

(c) (1) Prior to the installation of an automated drug delivery system, the facility and the pharmacy shall develop written policies and procedures to ensure safety, accuracy, accountability, security, and patient confidentiality, and to define access and limits to access to equipment and drugs.

(2) All policies and procedures shall be maintained at the location where the system is being used.

(d) Drugs dispensed from the automated drug delivery system shall be limited to the following:

(1) Drugs ordered by a prescriber for a patient of the facility for administration prior to the next scheduled delivery from the pharmacy, or 72 hours, whichever is less. These drugs shall be dispensed only upon authorization by a pharmacist after the pharmacist has reviewed the prescriber’s order.

1 (2) *Drugs that a prescriber has ordered for a patient*
2 *on an as needed basis, if the utilization of those drugs is*
3 *subject to the ongoing review by a pharmacist.*

4 (3) *Drugs designated by the patient care policy*
5 *committee or pharmaceutical service committee of the*
6 *facility as emergency drugs or acute onset drugs. These*
7 *drugs may be dispensed pursuant to the order of a*
8 *prescriber for emergency or immediate administration to*
9 *a patient of the facility.*

10 (e) *The stocking of an automated drug delivery*
11 *system shall be performed by a pharmacist. If the*
12 *automated drug delivery system utilizes removable*
13 *packets or drawers, the stocking system may be done*
14 *outside of the facility and be delivered to the facility if all*
15 *of the following conditions are met:*

16 (1) *The task of placing drugs into the removable*
17 *packets or drawers is performed by a pharmacist or by*
18 *pharmacy personnel under the direct supervision of a*
19 *pharmacist.*

20 (2) *The removable packets or drawers are transported*
21 *to the facility in a secure tamper-evident container.*

22 (3) *The facility, in conjunction with the pharmacy, has*
23 *developed policies and procedures to ensure that the*
24 *packets or drawers are properly placed into the*
25 *automated drug delivery system.*

26 (f) *Review of the drugs contained within, and the*
27 *operation and maintenance of, the automated drug*
28 *delivery system shall be done in accordance with law and*
29 *shall be the responsibility of the pharmacy. The review,*
30 *which shall be conducted on a bimonthly basis, shall*
31 *include a physical inspection of the drugs in the*
32 *automated drug delivery system, an inspection of the*
33 *automated drug delivery system machine for cleanliness,*
34 *and a review of the dispensing and stocking records in*
35 *order to verify the security and accountability of the*
36 *system.*

37 (g) *Drugs dispensed from an automated drug delivery*
38 *system that meets the requirements of this section shall*
39 *not be subject to the labeling requirements of Section*
40 *4076 of the Business and Professions Code or Section*

1 111480 of this code if the drugs to be placed into the
2 automated drug delivery system are in unit dose
3 packaging or unit of use and if the information required
4 by Section 4076 of the Business and Professions Code and
5 Section 111480 of this code is readily available at the time
6 of drug administration.

7 (h) This section shall become operative July 1, 1999.

8 ~~4177) is added to Chapter 9 of Division 2 of the Business~~
9 ~~and Professions Code, to read:~~

10
11 Article 12.5. Automated Drug Dispensing
12

13 ~~4177. As used in this article, “automated drug~~
14 ~~dispensing system” means a mechanical system that~~
15 ~~performs operations or activities, other than~~
16 ~~compounding or administration, relative to the storage,~~
17 ~~dispensing, or distribution of medications that collect,~~
18 ~~control, and maintain all transaction information as well~~
19 ~~as provide for security and accountability of drug~~
20 ~~products.~~

21 ~~4177.5. A pharmacy and a health facility licensed~~
22 ~~pursuant to subdivisions (c) and (d) of Section 1250 of the~~
23 ~~Health and Safety Code that have entered into an~~
24 ~~agreement for the provision of drugs to the patients of the~~
25 ~~facility may use an automated drug dispensing system~~
26 ~~located in the facility if all of the following conditions are~~
27 ~~met:~~

28 (a) ~~The drugs in the automated drug dispensing~~
29 ~~system are owned by the pharmacy until they are~~
30 ~~dispensed for patient use.~~

31 (b) ~~The automated drug dispensing system has~~
32 ~~adequate security systems and procedures, evidenced by~~
33 ~~written policies and procedures, to do the following:~~

34 (1) ~~Prevent unauthorized access.~~

35 (2) ~~Comply with federal and state regulations.~~

36 (3) ~~Maintain patient confidentiality.~~

37 (4) ~~Assure compliance with the requirements of this~~
38 ~~section.~~

39 (c) ~~Accountability for the drugs dispensed from the~~
40 ~~automated drug dispensing systems shall be the~~

1 responsibility of the pharmacist-in-charge of the
2 pharmacy.

3 (d) Filling and stocking of all medications in the
4 automated drug dispensing system shall be performed by
5 a pharmacist or pharmacy technician acting under the
6 direct supervision of a pharmacist. For purposes of this
7 section, “direct supervision” means the pharmacist shall
8 verify that the filling and stocking of the drugs is
9 replacement stock for drugs documented as dispensed
10 from the system.

11 (e) Drugs dispensed from the automated dispensing
12 system shall be limited to the following:

13 (1) Drugs ordered by a prescriber for a patient of the
14 facility for administration at a time prior to the next
15 readily scheduled delivery from the pharmacy.

16 (2) Drugs that a prescriber has ordered for a patient
17 on an as needed basis, provided the utilization of those
18 drugs is subject to ongoing review by a pharmacist.

19 (3) Drugs dispensed pursuant to the order of a
20 prescriber for emergency administration to a patient of
21 the facility.

22 (f) Except for drugs dispensed pursuant to paragraph
23 (3) of subdivision (e), access to the drugs in the
24 automated drug dispensing system shall require
25 authorization from a pharmacist who is an employee or
26 agent of the pharmacy and who has reviewed the
27 prescriber’s order.

28 (g) Review of the operation and maintenance of the
29 automated drug dispensing system shall be the
30 responsibility of the consultant pharmacist retained by
31 the licensed health facility. That review shall include a
32 physical inventory of the drugs in the automated drug
33 dispensing system and a review of the dispensing and
34 filling and stocking records no less than once every
35 calendar quarter in order to verify the security
36 accountability of the system.

37 4178. Jurisdiction over the ownership, security,
38 accountability, and any other aspect of the operation of
39 automated drug dispensing systems shall be with the
40 board. Other agencies with regulatory authority over

1 facilities licensed pursuant to subdivision (c) or (d) of
2 Section 1250 of the Health and Safety Code shall have
3 access to records consistent with their authority, and shall
4 report any problems with the operation of the system to
5 the board.

6 4178.5 An automated drug dispensing system that
7 meets the requirements of Section 4177.5 shall not be
8 construed to be an emergency supplies container as
9 defined in Section 1261.5 of the Health and Safety Code
10 and shall not be subject to any limitations imposed by that
11 section.

12 4179. Drugs dispensed from an automated drug
13 dispensing system that meets the requirements of Section
14 4177.5 shall not be subject to the labeling requirements of
15 Section 4076 or Section 111480 of the Health and Safety
16 Code if the automated drug dispensing system contains
17 the information required by those sections or if the
18 information is otherwise readily available at the time of
19 drug administration.

